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Docket No.: 21046-00056-US1

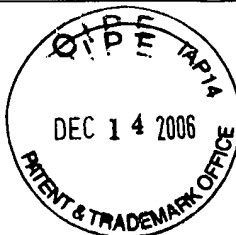
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Paul Watson et al.

Application No.: 10/575,228

Filed: April 7, 2006

For: BLISTER PACK LABEL



Confirmation No.:

Art Unit: N/A

Examiner: Not Yet Assigned

CLAIM FOR PRIORITY AND SUBMISSION OF DOCUMENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby claim priority under 35 U.S.C. 119 based on the following prior foreign application filed in the following foreign country on the date indicated:

<u>Country</u>	<u>Application No.</u>	<u>Date</u>
United Kingdom	0323576.9	October 8, 2003

In support of this claim, a certified copy of the said original foreign application is filed herewith.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 22-0185, under Order No. 21046-00056-US1 from which the undersigned is authorized to draw.

Dated:

December 14, 2006

Respectfully submitted,

By

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Brian J. Hairston

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Innovation

USA

The Patent Office
Concept House
Cardiff Road
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South Wales
NP10 8QQ

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Controller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

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**Statement of inventorship and of
right to grant of a patent**

The Patent Office

Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference

DB/3P03422P/BEP

2. Patent application number
(if you know it)

3. Full name of the or of each applicant

3Point Blue Limited

4. Title of the invention

BLISTER PACK LABEL

5. State how the applicant(s) derived the right
from the inventor(s) to be granted a patent

By contract of employment.

6. How many, if any, additional Patents Forms
7/77 are attached to this form?
(see note (c))

7.

I/We believe that the person(s) named over the page (and on
any extra copies of this form) is/are the inventor(s) of the invention
which the above patent application relates to.

Signature

Date

David Bailey 7/10/03

8. Name and daytime telephone number of
person to contact in the United Kingdom

DAVID BAILEY

01892 510600

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- d) When an application does not declare any priority, or declares priority from an earlier UK application, you must provide enough copies of this form so that the Patent Office can send one to each inventor who is not an applicant.
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Enter the full names, addresses and postcodes of the inventors in the boxes and underline the surnames

Jonathan Bobbett
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Patents ADP number *(if you know it):*

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Grove Haven
Hawkenbury Road
Tunbridge Wells
Kent
TN3 9AD

Patents ADP number *(if you know it):*

Reminder

Have you signed the form?

Patents ADP number *(if you know it):*

Patents Form 1/77

Patents Act 1977
(Rule 16)



0900T03 EB43161-13 000016
201/7700 0.00-0323576.9

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The Patent Office

Cardiff Road
Newport
South Wales
NP9 1RH

1. Your reference

DB/3P03422P/BEP

0323576.9

2. Patent application number

(The Patent Office will fill in this part)

08 OCT 2003

3. Full name, address and postcode of the or of each applicant (underline all surnames)

3Point Blue Limited
The Corn Exchange
Bank Street
Tonbridge
Kent, TN9 1BL

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

8728982001

4. Title of the invention

BLISTER PACK LABEL

5. Name of your agent (if you have one)

BROOKES BATCHELLOR LLP

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

102-108 CLERKENWELL ROAD
LONDON
EC1M 5SA

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08142291001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
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Date of filing
(day / month / year)

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

YES

- a) any applicant named in part 3 is not an inventor, or
 - b) there is an inventor who is not named as an applicant, or
 - c) any named applicant is a corporate body.
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Continuation sheets of this form	--
Description	6 /
Claim(s)	3 /
Abstract	1 /
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10. If you are also filing any of the following, state how many against each item.

Priority documents	--
Translations of priority documents	--
Statement of inventorship and right to grant of a patent (<i>Patents Form 7/77</i>)	3 /
Request for preliminary examination and search (<i>Patents Form 9/77</i>)	--
Request for substantive examination (<i>Patents Form 10/77</i>)	--
Any other documents (<i>please specify</i>)	--

11.

I/We request the grant of a patent on the basis of this application.

Signature

David Bailey

Date

7 October 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

DAVID BAILEY

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BLISTER PACK LABEL

The present invention relates to a label for a blister pack. In particular, it relates to a label which makes it more difficult for a child to release a medicament from the blister pack without making it unduly difficult for the elderly or infirm to remove the medicament.

Conventional blister cards or packs typically include a plastics sheet material moulded to provide a plurality of recesses into each of which recesses is placed a medicament, typically in tablet or capsule form. The medicaments are held in place by means of a foil retaining sheet. When the patient wishes to use the medicament, they push the tablet or capsule through the foil retaining sheet. For ease of release, the foil retaining sheet is usually rather thin and easily ruptured. This raises issues of child safety as it becomes very easy for a child to tamper with the blister pack, so releasing the medication. One approach to improving the child-resistance of a blister pack is to increase the thickness of the foil in order to require greater strength in order to push the medicament through the foil retaining sheet. However, one needs to be careful to avoid producing a blister pack from which elderly or infirm might find it impossible to gain access to their medicament.

Accordingly, there is a need to provide a blister card that provides resistance to tampering by children but allows the elderly or infirm to release their medicament without undue difficulty. WO 02/32666 describes one approach in which a first sheet material is attached to the foil of a conventional blister pack by a temporary adhesive. The first sheet covers all of the individual medicament recesses, but is itself of smaller overall dimensions than the blister pack itself. Overlaying the first sheet is a second sheet material. This is provided with a permanent adhesive and is larger than the first sheet material such that where it overlies the first sheet, it is adhered thereto by the permanent adhesive, but where it does not overlie the first sheet, it adheres by the permanent adhesive to the foil retaining sheet of the

blister pack. The second sheet is perforated or scored in the area around where it overlies each medicament recess. The user peels off a portion of the second sheet adjacent the location of a medicament. The perforations ensure selective removal only of that part adjacent the chosen medicament and the use of a permanent
5 adhesive provides that a respective portion of the first sheet material is also removed. The user can then press the medicament through the foil layer as usual.

However, the arrangement of WO 02/32666 requires careful cutting and assembly of the components. The present invention seeks to provide an alternative blister
10 pack label.

In its broadest sense, the present invention provides a medicament blister pack label comprising a first sheet having first and second faces and a second sheet having first and second faces, wherein the first face of the second sheet and the
15 second face of the first sheet are opposed and bonded together and wherein at least portions of the first face of the first sheet are provided with a permanent adhesive. The sheet includes lines of weakness defining medicament release zones.

In one embodiment, the first face of the first sheet is fully coated with a permanent
20 adhesive.

In an alternative embodiment, the first face of the first sheet is provided with a permanent adhesive only in those areas not adjacent to the medicament release zones. In a modification to this embodiment, those areas upon which a permanent
25 adhesive is not provided are provided with a temporary or removable adhesive.

Suitably, the permanent adhesive is an acrylic emulsion adhesive. Alternatively, the adhesive may be a spirit-based permanent adhesive.

Suitably the first and second sheets are bonded by means of a permanent adhesive.
30

Typically, the lines of weakness defining medicament release zones comprise perforations or slits. Preferably, the lines of weakness penetrate the full thickness of the label.

5

Preferably, the label further comprises a release sheet or backing paper opposing the first face of the first sheet. Suitably, the release sheet or backing paper comprises a sheet material having a silicone coating.

10 Preferably, the first sheet is a synthetic material, more preferably a polymeric or plastics sheet material. Most preferably, the first sheet is a polyethylene or polypropylene sheet. Most preferably still, the first sheet is a bi-directional polypropylene sheet material.

15 Preferably, the first sheet has a weight of from 15 to 100 g/m²; more preferably from 20 to 50 g/m²; even more preferably about 30 g/m².

Preferably, the first sheet has a thickness of from 15 to 20µm; more preferably from 20 to 60µm; even more preferably about 30µm.

20 Preferably, the second sheet is a printable material, more preferably a paper material. Suitably the paper material is a machine-coated or blade-coated paper. Preferably, the paper has a weight of 50g/m² or more, more preferably from 50 to 400g/m²; even more preferably from 60 to 200g/m², most preferably from 70 to 150g/m². Advantageously, the paper has a weight of from 80 to 120g/m², suitably
25 about 85g/m².

Preferably, the second sheet has a thickness of from 50 to 400µm; more preferably from 50 to 150µm; even more preferably from 60 to 100µm.

The above and other aspects of the present invention will now be illustrated in further detail, by way of example only, with reference to the accompanying drawings in which:-

5 Figure 1 is a schematic sectional view of a first embodiment of a label in accordance with the present invention;

Figure 2 is a schematic sectional view of a conventional blister pack;

10 Referring to Figure 2, there is shown a conventional blister pack 10 comprising a moulded plastics tray 11 including a plurality of moulded cavities or recesses 12 each containing a medicament in the form of a capsule or tablet 13. The tablets are held in place by means of a foil retaining sheet 14. Retaining sheet 14 is adhered to tray 11 by means of adhesive 15 applied to the tray.

15 A first embodiment of a label 20 in accordance with the present invention is shown in Figure 1. The label includes a first label sheet 21 bonded to a second label sheet 22. In the embodiment shown, the first and second label sheets are bonded by means of an adhesive layer 23. However other means of bonding may
20 be suitable, for example, corona discharge, depending upon the nature of the materials constituting the first and second sheets 21,22.

In the preferred embodiment, first sheet 21 is a polymeric material such as polyethylene or polypropylene. A bi-directional polypropylene sheet having a
25 thickness of about 50-60 μ m and a weight (or grammage) of about 60 g/m² is particularly suitable.

Second sheet 22 is preferably a sheet material having a printable surface, such as a paper material. Wood or pulp based materials are particular preferred, but
30 synthetic materials, such as Tyvek (Reg T.M.) are equally useable. Coated papers,

such as gloss or semi-gloss machine-coated or blade-coated papers are preferred, such as semi-gloss machine coated paper having a thickness of about 75 μ m and a weight (grammage) of 80-90 g/m².

A permanent adhesive 24 is applied to the exposed surface of first sheet 21. Any adhesive composition compatible with the material from which first sheet 21 is formed is suitable. For example all acrylic emulsion adhesive is suitable for use with a polypropylene sheet 21.

Lines of weakness 30 such as perforations or slits are formed in the label to define a plurality of medicament release zones 31, each zone 31 corresponding to the location of a medicament when the label is applied to the blister pack 10.

Figure 3 shows, in views (a) to (h) a number of exemplary lines of weakness 30 formed in labels 20 of the present invention. The lines of weakness can range from simple lines of slits (3c), crosses (3b), and circles (3a) of slits, to more complex arrangements such as those shown in Figures 3d to 3h.

Figure 4 illustrates the use of the label 20 of the present invention applied to a blister pack 10 containing a medicament 11. In use, the patient applies a force to the underside of the blister pack adjacent a recess 12 (as shown by Arrow A). The force applied allows the label 20 to fracture along the lines of weakness 30 and allows, in a conventional manner, the tablet 11 to perforate the foil 14 of the blister pack 10, so releasing the tablet 11.

An alternative embodiment is illustrated in Figure 5. In this embodiment, those areas of the first sheet 21 forming the medicament release zone are not provided with any adhesive. A yet further alternative embodiment is illustrated in Figure 6 in which those areas of the first sheet 21 forming the medicament release zone are provided with a temporary adhesive 40.

The absence of adhesive or use of a temporary adhesive means that the label can be used either as a peel-away label of the type described in WO 02/32666 or as the push-through type described above.

- 5 The sheet of the present invention may include further bonded layers intermediate the first 21 and second 22 layers described above.

The use of a printable second layer 22 allows patient information and/or product branding material to be printed onto the label 20.

Claims.

1. A medicament blister pack label comprising a first sheet having first and second faces and a second sheet having first and second faces, wherein the first face of the second sheet and the second face of the first sheet are opposed and bonded together; wherein at least portions of the first face of the first sheet are provided with a permanent adhesive; and wherein the sheet includes lines of weakness defining medicament release zones.
2. A medicament blister pack label as claimed in Claim 1 wherein the first face of the first sheet is fully coated with a permanent adhesive.
3. A medicament blister pack label as claimed in Claim 1 wherein the first face of the first sheet is provided with a permanent adhesive only in those areas not adjacent to the medicament release zones.
4. A medicament blister pack label as claimed in Claim 3 wherein those areas upon which a permanent adhesive is not provided are provided with a temporary or removable adhesive.
5. A medicament blister pack label as claimed in any one of claims 1 to 4 wherein the permanent adhesive is an acrylic emulsion permanent adhesive or a spirit-based permanent adhesive.
6. A medicament blister pack label as claimed in any preceding claim wherein the first and second sheets are bonded by means of a permanent adhesive.
7. A medicament blister pack label as claimed in any preceding claim wherein the lines of weakness defining medicament release zones comprise perforations or slits.

8. A medicament blister pack label as claimed in claim 7 wherein the lines of weakness penetrate the full thickness of the label.
- 5 9. A medicament blister pack label as claimed in any preceding claim wherein the label further comprises a release sheet opposing the first face of the first sheet.
- 10 10. A medicament blister pack label as claimed in Claim 9 wherein the release sheet comprises a sheet material having a silicone coating.
- 11 11. A medicament blister pack label as claimed in any preceding claim wherein the first sheet is a synthetic material, more preferably a polymeric or plastics sheet material.
- 15 12. A medicament blister pack label as claimed in Claim 11 wherein the first sheet is a polyethylene or polypropylene sheet, preferably a bi-directional polypropylene sheet material.
- 20 13. A medicament blister pack label as claimed in any preceding claim wherein the first sheet has a weight of from 15 to 100 g/m²; preferably from 20 to 50 g/m²; more preferably about 30 g/m².
- 25 14. A medicament blister pack label as claimed in any preceding claim wherein the first sheet has a thickness of from 15 to 20µm; preferably from 20 to 60µm; more preferably about 30µm.
15. A medicament blister pack label as claimed in any preceding claim wherein the second sheet comprises a printable material.
- 30 16. A medicament blister pack label as claimed in claim 15 wherein the second sheet is a paper material.

17. A medicament blister pack label as claimed in any preceding claim wherein second sheet has a weight of 50g/m^2 or more, preferably from 50 to 400g/m^2 ; more preferably from 60 to 200g/m^2 , most preferably from 70 to 150g/m^2 .

5

18. A medicament blister pack label as claimed in Claim 17 wherein second sheet has a weight of from 80 to 120g/m^2 , preferably about 85g/m^2 .

19. A medicament blister pack label as claimed in any preceding claim wherein the second sheet has a thickness of from 50 to $400\mu\text{m}$; preferably from 50 to $150\mu\text{m}$; more preferably from 60 to $100\mu\text{m}$.

10

20. A medicament blister pack label substantially as described herein with reference to the accompanying drawings.

15

Abstract

BLISTER PACK LABEL

5 The present invention relates to a label for a blister pack. In particular, it relates to
a label which makes it more difficult for a child to release a medicament from the
blister pack without making it unduly difficult for the elderly or infirm to remove
the medicament. We describe a medicament blister pack label comprising a first
sheet having first and second faces and a second sheet having first and second
10 faces, wherein the first face of the second sheet and the second face of the first
sheet are opposed and bonded together; wherein at least portions of the first face
of the first sheet are provided with a permanent adhesive; and wherein the sheet
includes lines of weakness defining medicament release zones.

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FIG 1

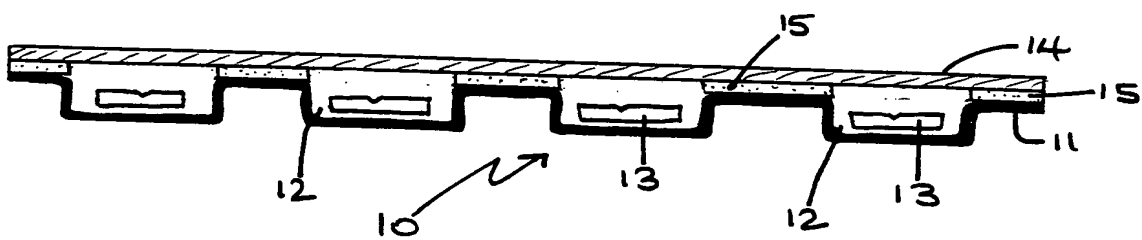
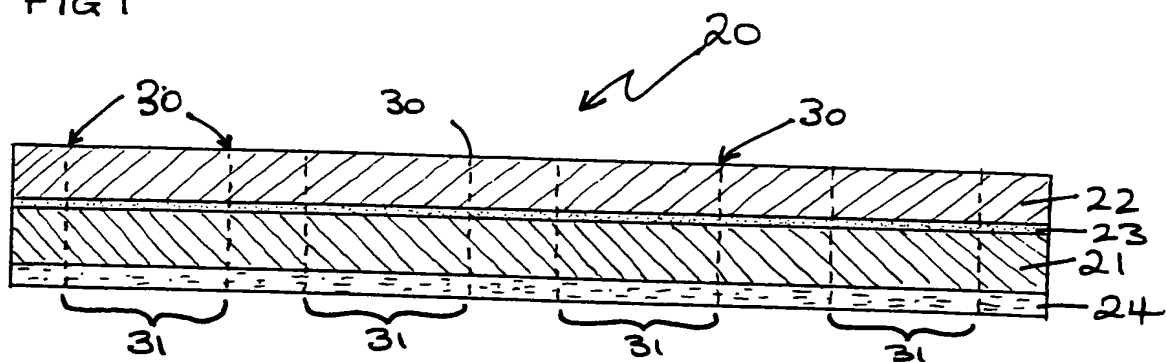


FIG 2

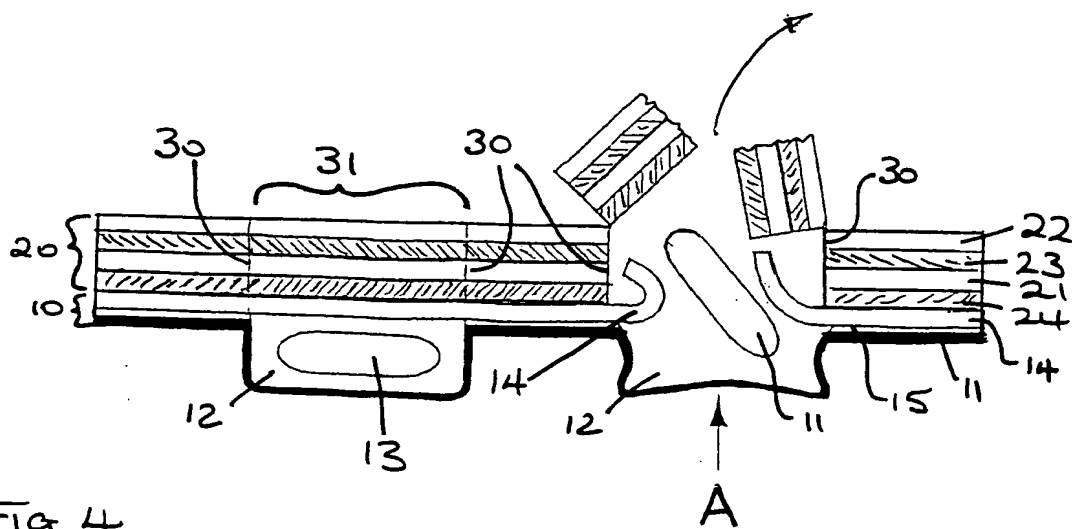
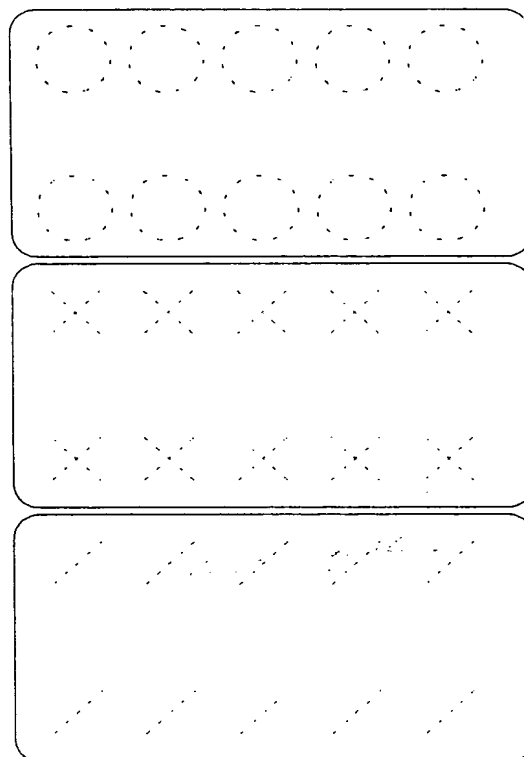


FIG 4

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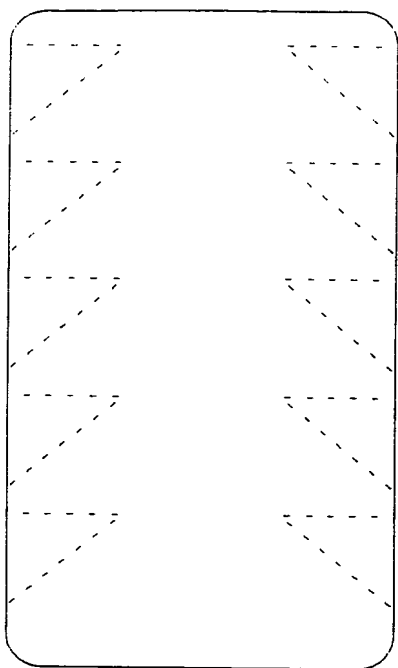
a

b

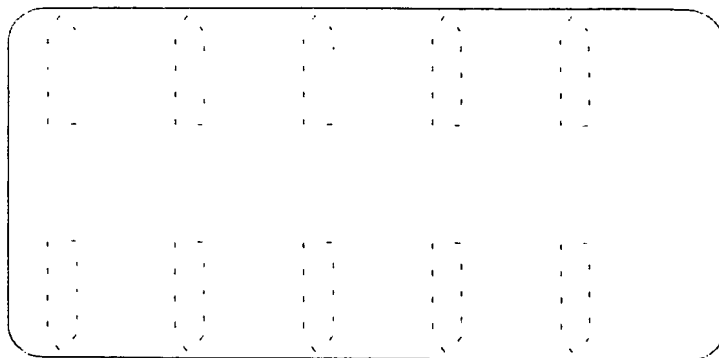
c

fig 3

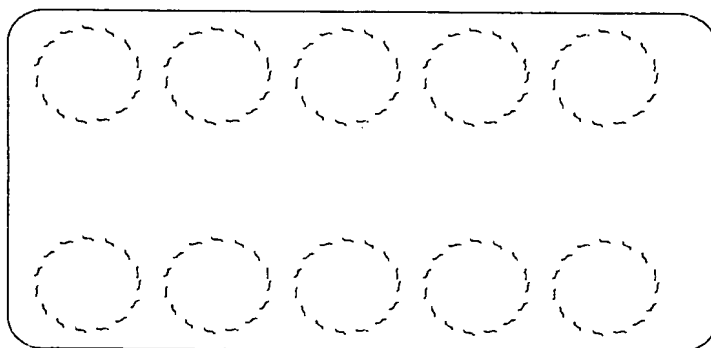
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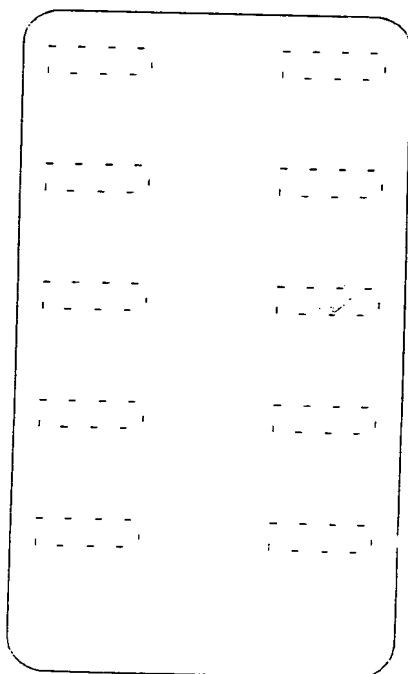
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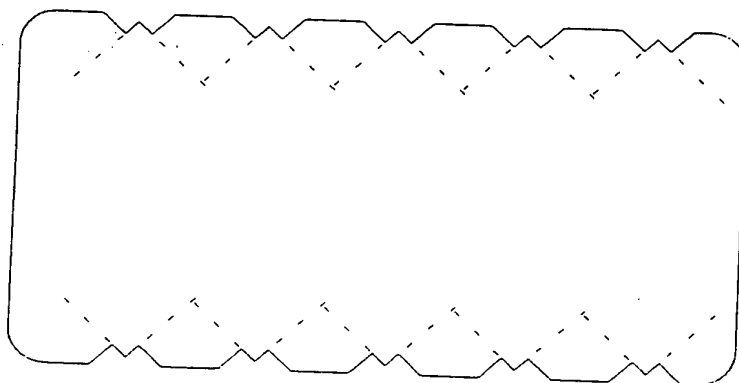
f



g



e



h

Fig 3.

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Fig 5

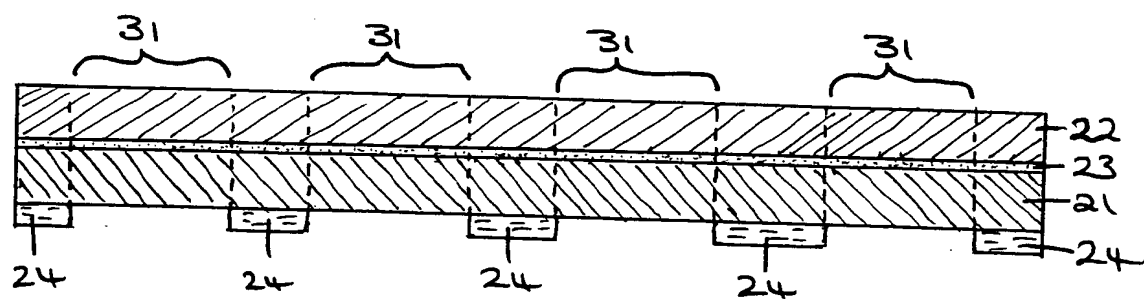
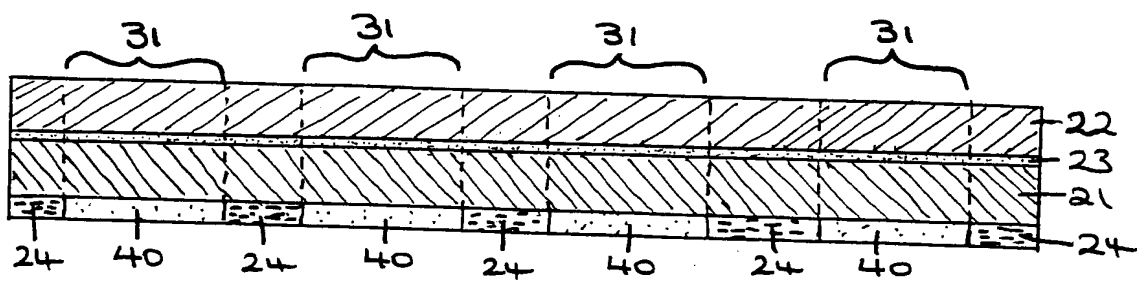


Fig. 6.



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